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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,376	07/01/2003	John S. Patton	0005.15	3703
21968	7590	07/14/2005	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,376

Applicant(s)

PATTON ET AL

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 4-25-05 is acknowledged.

In view of the cancellation of claims 1-25 by a preliminary amendment which claims were inadvertently included in the prosecution, the previous action is vacated. The following is the new action.

Claims included in the prosecution are 26-43.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,685,967. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both patent and instant application are drawn to the same process of preparation of the insulin powder compositions and the insulin powders.

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The patented process claims 1-5 and the composition claims 6-9 and instant claims differ only in the particle sizes; the patented claims recite the sizes of 0.1 to 5 micrometers whereas instant claims recite 'size below 10 microns'. This limitation anticipates the patented size ranges. Furthermore, it would have been obvious to of ordinary skill in the art to vary the process conditions to prepare sizes between 5 and 10 microns with a reasonable expectation of success since the particle sizes depend on the size of the nozzle. The patented process claims 10-13 and the product claims 14-18 recite the same limitations as in instant claims differing in the insulin amounts. Instant claims are generic with respect to insulin amounts and it would have been obvious to one of ordinary skill in the art to vary the insulin amounts and obtain the desired amounts since it depends upon the amounts of the salts present in the buffer solution and the other carriers added.

3. Claims 26-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 6,582,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. The claims in both patent and instant application are drawn to the same process of preparation of the insulin powder compositions and the insulin powders. The patented claims are generic with respect to the sizes of the particles and the pharmaceutically active agent and therefore, the patented claims anticipate instant active agent and the sizes. The patented claims recite specific spray drying process conditions such as 50 to 200 degrees and the carrier molecules such as carbohydrates, peptides etc. Instant claims are generic with respect

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to spray drying temperatures. It would have been obvious to one of ordinary skill in the art to vary the spray drying conditions since selecting a suitable temperature would depend upon the stability of the active agent to the temperature to which it is subjected to. It would be obvious to one of ordinary skill in the art to include the carrier molecules to provide bulk as instant dependent claims also recite the same carrier molecules.


4. Claims 31-34 and 39-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-57 of copending Application No. 10/141,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both copending application and instant application are drawn to the same insulin powder composition. Instant claims are generic with respect to the buffer and the claims in the copending application recite citrate buffer. It would have been obvious to one of ordinary skill in the art to choose an appropriate buffer to maintain the pH of the medium at which insulin maintains its biological activity without degradation. The claims in the copending application recite specific insulin amounts. Instant claims are generic with respect to insulin amounts and it would have been obvious to one of ordinary skill in the art to vary the insulin amounts and obtain the desired amounts since it depends upon the amounts of the salts present in the buffer solution and other carriers added.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK